Amended Annual Report – FY 2008

MAR 0 3 2009

This report is required by law (? USC 21 43) Failure to report according to the regulations can result in an order to cease and desist and to be subject lo penalties as provided for in Section 2150

Set reverse side for additionalinformation

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1 REGISTRATION NO. 21-R-0076 / 331

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA inolude Zip Code)

MAIMONIDES MEDICAL CENTER
4802 10th Avenue
Brooklyn, NY 11219
Telephone: (718) 283-8439

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITYLOCATIONS (Sites)

Maimonides Medical Center

4802 10th Ave, Brooklyn, NY 11219

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in those animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs			31	1	32
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			12		12
9. Non-human Primates					
10. Sheep					
11., Pigs		1	25		26
12. Other Farm Animals					
13 Other Animals					
Rats			12		12
Mice			148		148

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarianfor this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGN

(b)(6), (b)(7)c

DATE SIGNED 2/27/09

APHI

NP

Amended Explanation – FY 2008

MAR 4 2 2009

FY 2008 APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: **21-R-0076 / 331**

2. Number of animals used in this study. **12**

3. Species (common name) of animals used in the study. ***Rabbit***

4. Explain the procedure producing pain and/or distress.

Rabbit distal femur (bilaterally) will be shaved. Animals will then be brought to the OR, draped and prepped with betadine at the surgical site. After induction of anesthesia, a midline longitudinal incision and medial arthrotomy with lateral subluxation of the patella will be performed. Then, a full-thickness (2-mm-deep), 3-mm-diameter femoral osteochondral defect using a Dremel power tool under steady irrigation will be drilled in the femoral trochlear groove. Each defect (except untreated controls) will then be implanted with a collagen sponge containing granulin or bone morphogenetic protein, or no additive. Controls will receive no implant. The patella will be reduced, and the wound closed in layers with 3.0 or 4.0 vicryl or other resorbable suture material. The implants are held in place, in the defect, by the patella when the patella is put back into place. Upon awakening, rabbits will be allowed unrestricted cage or floor movement.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For federally mandated testing, see question 6 below)

*This protocol was approved by the IACUC as a category "E" because of the **potential** for pain or distress **not** relieved with anesthetics, analgesics and/or tranquilizer drugs or other methods for relieving pain or distress once the post-operative period was passed.*

In actuality, the protocol required the use of analgesia (Carprofen 4 mg tab, 1x/day) on day of surgery and 7 days post-operatively. Total time of survival post-surgery was 12 weeks. The only medication excluded from use was "steroidal" anti-inflammatories. Each of the 12 rabbits received the analgesic and no pain or distress was noted during the 11 weeks remaining on the study.

Keeping in line with the USDA definitions these animals should have been designated category "D".

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Not applicable.

NP

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 21-R-0076/331

2. Number 1 of animals used in this study.

3. Species (common name) Dogs of animals used in the study.

4. Explain the procedure producing pain and/or distress.

The surgery performed produces partial cardiomyectomy thereby reducing the size of the stomach. This results in the development of Gastroesaphageal Reflex (GER). It is the GER that may result in the subject experiencing some distress such as stomach upset and upper airway swelling. Actual observation has shown no adverse effects in the subject population to-date in those subjects that developed GER.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

The essence of the study is to monitor the onset the GER through pH measurement, observe any effects in the upper airway, and measure airway resistance. Treating for GER would neutralize the effects of GER and it's relationship to the upper airway. Measurements would not yield valid data to either prove or disprove the hypothesis.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency Not Applicable CFR

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 21-R-0076
CUSTOMER NUMBER: 331

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Maimonides Medical Center
4802 10th Avenue
Brooklyn, NY 11219

Telephone: (718) -283-8439

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessary or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs			31	1	32
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits				12	12
9. Non-human Primates					
10. Sheep					
11. Pigs		1	25		26
12. Other Farm Animals					
13. Other Animals					
RATS			12		12
MICE			148		148

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIG

(b)(6), (b)(7)c

DATE SIGNED 11/24/08

APH

DEC 01 2008